Written Testimony

Of

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Fort Wayne, Indiana

Presented on 11 July, 2006

before the

109th Congress of the United States

House of Representatives

Subcommittee on Criminal Justice, Drug Policy and Human Resources

Committee on Government Reform

Chairman Souder, Members of the Subcommittee and Staff. It is with great pleasure and honor that I sit before you today. From childhood, it was ingrained into my life that Godly character was vital to success in life and that type of character was to include civic responsibility. So I want to humbly say Thank You, for the privilege of serving you here today and testifying concerning the matter of security within the pharmaceutical supply chain. I would ask at this time that you enter my provided written testimony into the record.

I come before you today as one with close to a decade of experience in the use and integration of Radio Frequency Identification, otherwise known as RFID. Our team at Northern Apex has utilized the technology in the areas of manufacturing, security, inspection and state government as well as pharmaceutical. Our organization has never received any federal funds for research or as a developer related to this technology or any other effort. We are an experienced stake holder by virtue of the customers for whom we have and will continue to work with concerning the use of RFID for tracing their drugs through the supply chain.

As RFID project manager for Northern Apex, I led what many consider the world's first pharmaceutical supply chain production use of RFID. We worked with Purdue Pharma L.P and other technology providers to implement a process which placed smart labels on Purdue's popular pain medication, Oxycontin. The solution was able to identify individual bottles on the production line at speeds of 150 bottles per minute. A sealed, tamper-evident case of 48 individual bottles could be verified in less than 5 seconds. Since that time, I have been directly involved in designing several pharma manufacturing implementations that are using RFID today in production.

These efforts have led to interactions with companies from many aspects of the pharmaceutical supply chain including label manufacturers, packagers, distributors, bottle handling equipment, drug manufacturers, as well as business intelligence software providers.

This experience has provided significant interaction with the processes a drug manufacturer is required to follow to in order to produce a drug that is FDA approved. The Code of Federal Regulations Title or Part 21 addresses at great length, good manufacturing processes, software validation and the overall accountability of the manufacturer to provide a safe, consistent, high quality product to the market.

The discussion at hand regarding the security of the pharmaceutical supply chain is not about how bad the existing process is but rather ways for us to improve an already reliable process when examined from a pure percentage standpoint. We have some of the best pharma manufacturers and distributors in the world within our borders and the relative number of incidents to overall production and prescriptions is low but clearly increasing. I cannot speak to the level or overall risk associated with counterfeiting, dilution, removal, modification and re-introduction, theft or other things which have occurred in the drug supply chain.

However, just by the fact that we are having this hearing, it is clear that there is reason to consider what happens to those drugs, once they leave the manufacturer and enter the distribution and wholesale chain.

While I'm not able to address the specific risk levels, I am qualified to speak concerning the technologies available to us, which when combined, could have a significant impact on the way trading is accomplished in the pharmaceutical industry.

As we examine options which could be utilized to influence the chain of custody of a controlled substance, there several things to consider. First, many technologies exist today which can further bolster the security of the drug supply.

Presently millions of electronic transactions are already being utilized in the world daily that allow us to ascertain the chain of events related to a website visit, a trade on Wall Street, along with hundreds of other everyday interactions. The FDA has already addressed using this type of technology in its description of an electronic or e-pedigree. This electronic transaction recording the chain of custody for a drug is a significant improvement over the paper pedigree of today.

The FDA's June 8, 2006 Counterfeit Drug Task Force report highlighted an important choice to no longer delay the cut-in date requirement of some existing pedigree requirements. This is a great initial move towards tightening the security of our drug supply chain.

There are however additional means that could complement the "traceable" transaction. These could be overt and covert. They could involve monitoring the Item, Case, Pallet and even Shipment Trailer level.

By using the group of technologies known as Auto-Identification, it is practical and real to consider having a track and trace unique serial number or ID associated with every bottle, case and pallet. As each lower level item is assembled into the next larger shipping unit, they would automatically be associated, recorded to a database and used to enhance the electronic pedigree. This is the basis of the RFID schemes presently being utilized by GlaxoSmithKline, Pfizer, Purdue Pharma and others.

It is also real to have the shipping company associate the trailer which contains a shipment, to their on board GPS and tele-matics systems to trace real time status of a controlled substance shipment. This is much like how you can trace today whether or not your UPS or FedEx package is out for delivery or has already been delivered. Many freight companies already have means for tracing their tractor-trailer rigs in real time using combined tele-matics and GPS technologies.

Other technologies such as 2-D barcodes and biometrics could also be implemented at key spots in the supply chain. Are all of these practical or necessary? That is yet to be determined by the extent to which we see the threat.

Secondly, many of these technologies are being implemented today by many different industries and organizations. The DOD has already seen the value of these Auto-ID technologies, utilizing them in battlefield logistics and has mandated their suppliers to begin using the technology for incoming shipments to their receiving locations.

We are not talking about technology that is light years away. In every instance that I've described, the different technologies exist today, which when combined, could provide a framework for an exponential improvement in the security of the drug supply chain.

Related to these technologies, there are some obstacles to the rapid widespread adoption. The RFID and Pharma industries have an ongoing debate over the value of certain modes and frequencies of RFID operation. There are clear reasons which begin to explain the debate but certainly only time and testing will provide true understanding. While I would not accuse the RFID manufacturers of any wrong doing, they are all clearly pushing their respective product to be the technology of choice for the industry. As a business' focused on success, it is in their best interest to see it become the standard. Pressing the adoption

of their specific technology, in effect creates a consumable, one-time use item. Item level serialization for each bottle of pills equals a lot of bottles that would require a tremendous number of smart labels. This process leads to innovation and healthy competition and is good for the RFID industry as well as those who use the technology.

Even with these uncertainties, the RFID and Pharma industries have combined to successfully implement item level track and trace using the two primary technologies. Pfizer tracks Viagra with item level tags of the High Frequency (HF) type and Ultra High Frequency (UHF) case tags. GlaxoSmithKline uses the same mix of item level and case level RFID technologies. Purdue Pharma has implemented the technology using item level tags of the UHF type. At this time, either technology is capable of providing schemes for traceability.

As you would expect, there are plusses and minuses to each. It's my belief that this body should not involve itself with that level of discussion. It would be the equivalent of deciding VHS versus Beta some twenty years ago.

However, with a vision towards broader adaptation, this body might consider whether or not further federal regulations should mandate the extent, description and complexity of the electronic drug pedigree track and trace efforts.

While there has been a level of adoption by certain states of the pedigree concept, there are clearly different opinions of how that pedigree should be manifested from Florida to California to Indiana. This leads to confusion on the part of both the distributors and the drug manufacturers as to how the pedigree should be accomplished. Leaving the core manifestation to the states could result in 50 different ways that a manufacturer has to provide their pedigree information. The FDA has provided excellent leadership and put a

significant amount of work and effort into annual reports, conferences with industry representatives and the overall education related to these concerns. Other organizations, like ePC Global, have health and life science action groups consisting of drug manufacturers, distributors, technology providers and integrators who are also attempting to answer these questions.

Do the FDA and Congress wait for the industry to gradually adopt ever increasing technologies? Much like the Wal-Mart RFID initiative for their top suppliers to incorporate case and pallet level RFID, its widespread adoption probably won't occur until the line in the sand is drawn by either the FDA or some form of legislation.

The June 2006 FDA report mentioned earlier does an excellent job detailing other concerns related to the broad adoption of the RFID component. These include database items, privacy concerns, labeling information and the like. While these are all items to be addressed, they should be viewed as hurdles in a race rather than obstacles that can't be overcome.

As part of the Committee on Government Reform, you are keenly aware that there is always a cost to change. The question is whether or not the risk and return make it valuable. There is not a quick easy answer to this question. Still, one factor that should minimize the overall cost of traceability is the reality that there are companies world wide, both inside and outside the pharma space, who use RFID and other auto identification schemes every day in their business. That number is constantly growing. Does the risk warrant the effort? There is no question that people's lives have been greatly affected by the issue at hand. Cancer, HIV patients and others have been the

victims of selfish, greedy people who would compromise their integrity for financial gain. The cost to some has been their life.

We know that some foreign and domestic counterfeiters have created the fine art of turning gypsum or the equivalent of drywall dust into tablets which look so much like the real medication that you have to analyze them to be sure. What keeps someone from introducing a poison instead of gypsum?

With the instances of breach which have already occurred, it is not out of the question to see the Pharmaceutical Supply Chain as a means for hostiles, whether foreign or domestic, to subtly attack the populace before being discovered.

We have addressed anthrax, small pox and other biological items through the development and advancement of drugs like Cipro. Yet the supply chain for the drugs used everyday could be susceptible to introduction of similar bioterrorism schemes. It is for good reason that the recent FDA report recommends that the countermeasure drug chain begin using these technologies.

The US is not alone. This is a global issue. Similar counterfeiting activities are happening world wide. With the onset of the internet pharmacy, people worldwide are at risk. Although many informed people don't purchase their medications in this manner, the sheer presence of this market provides a means for the propagation of such medical counterfeits.

To what level should we intervene is for you to determine. In general, I am not an advocate of the federal government creating more laws, which require more people to enforce them and result in greater costs to the end user. However, there are ways we can put controls in place which leverage technologies of the day. It could radically improve

over the present system and further minimize the risk, without adding exorbitant cost to the product. Savings could be realized in areas other than the intended or obvious.

Are Radio Frequency Identification and other technologies the end all to fix this issue? Surely not! Deception, greed and evil have been around since the Garden of Eden. I believe it will continue until the end of the civilization as we know it.

In the same way some have misused the drugs created to help and heal; other nefarious individuals will use and pervert the technologies and solutions we are discussing today. The enemies of a safe drug supply chain, whether greed or hostility based, are clearly getting smarter. They are leveraging ever increasing levels of technology and the good guys should pursue doing the same.

In summary, the existing US drug supply chain is the best in the world and has been very successful. While it is the best, there are technologies that offer opportunities for greater security in the supply chain that would benefit the customer and the industry. There will continue to be changes in the current technologies that are available today, but this should not impede making advances today with vision for how technology of the future could also enhance the process. Finally, there is a clear risk to the drug supply from both a hostile and a greed based criminal. This risk is growing and shouldn't be ignored.

Mr. Chairman, and Subcommittee members, again Thank you for the privilege of testifying here today. I am open to questions that you may have.